

Tae Hee HA, et al.  
Atty. Dkt.: Q94600  
Preliminary Amendment

## **AMENDMENTS TO THE CLAIMS**

**This listing of claims will replace all prior versions and listings of claims in the application:**

### **LISTING OF CLAIMS:**

Claims 1-3. (canceled).

4. (currently amended): ~~The mutual salt of claim 1A crystalline hydrate of raloxifene bisphosphonate, which is selected from the group consisting of crystalline 5/2hydrate of raloxifene 1/2etidronate 5/2hydrate, crystalline trihydrate of raloxifene pamidronate, crystalline pentahydrate of trihydrate, raloxifene alendronate, crystalline trihydrate of pentahydrate, raloxifene risedronate-trihydrate, crystalline monohydrate of raloxifene incadronate monohydrate, or and crystalline tetrahydrate of raloxifene zoledronate tetrahydrate.~~

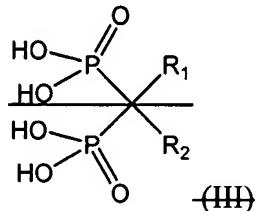
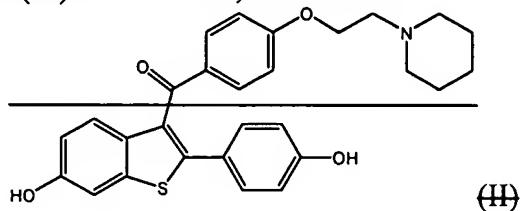
5. (currently amended): ~~The mutual salt of claim 1crystalline hydrate of claim 4, which is crystalline pentahydrate of raloxifene alendronate pentahydrate.~~

6. (currently amended): ~~The mutual saltcrystalline hydrate of claim 5, whose powder X-ray diffraction spectrum ( $I/I_0 \geq 20$ ) shows at 2 $\theta$  values of  $4.2 \pm 0.2$ ,  $8.4 \pm 0.2$ ,  $9.4 \pm 0.2$ ,  $9.7 \pm 0.2$ ,  $10.8 \pm 0.2$ ,  $13.3 \pm 0.2$ ,  $13.8 \pm 0.2$ ,  $14.2 \pm 0.2$ ,  $16.7 \pm 0.2$ ,  $18.3 \pm 0.2$ ,  $18.6 \pm 0.2$ ,  $19.4 \pm 0.2$ ,  $19.8 \pm 0.2$ ,  $20.5 \pm 0.2$ ,  $20.8 \pm 0.2$ ,  $21.2 \pm 0.2$ ,  $21.6 \pm 0.2$ ,  $25.5 \pm 0.2$  and  $26.9 \pm 0.2$ .~~

7. (currently amended): ~~The mutual saltcrystalline hydrate of claim 14, which is crystalline trihydrate of raloxifene risedronate-trihydrate.~~

8. (currently amended): ~~The mutual saltcrystalline hydrate of claim 7, whose powder X-ray diffraction spectrum ( $I/I_0 \geq 20$ ) shows at 2 $\theta$  values of  $6.8 \pm 0.2$ ,  $10.3 \pm 0.2$ ,  $12.3 \pm 0.2$ ,  $15.2 \pm 0.2$ ,  $16.5 \pm 0.2$ ,  $17.0 \pm 0.2$ ,  $17.3 \pm 0.2$ ,  $17.7 \pm 0.2$ ,  $20.3 \pm 0.2$ ,  $20.9 \pm 0.2$ ,  $21.2 \pm 0.2$ ,  $19.4 \pm 0.2$ ,  $19.8 \pm 0.2$ ,  $20.5 \pm 0.2$ ,  $20.8 \pm 0.2$ ,  $21.2 \pm 0.2$ ,  $21.6 \pm 0.2$ ,  $25.5 \pm 0.2$  and  $26.9 \pm 0.2$ .~~

9. (currently amended): A process for preparing ~~a mutual salt of the crystalline hydrate of raloxifene and bisphosphonic acid of formula (I)bisphosphonate of claim 4~~, which comprises the step of reacting a ~~compound of formula (II)raloxifene free base~~ or its solvate with a ~~compound of formula (III) or its solvate~~, in a solvent:

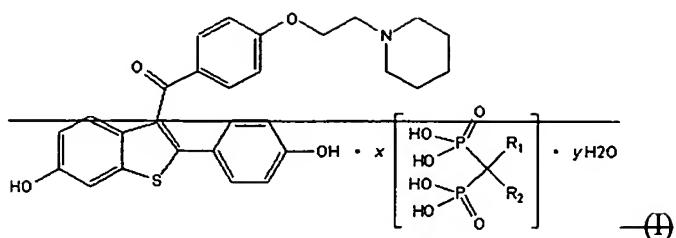


wherein  $R_1$  and  $R_2$  have the same meanings as defined in claim 1 ~~bisphosphonic acid selected from the group consisting of etidronic acid, pamidronic acid, alendronic acid, risedronic acid, incadronic acid and zoledronic acid, or its solvate, in a solvent.~~

10. (currently amended): The ~~process~~ of claim 9, wherein the solvent is selected from the group consisting of water, methanol, ethanol, propanol, isopropanol, acetone, tetrahydrofuran, 1,4-dioxane, acetonitrile, N,N-dimethylformamide, and a mixture thereof.

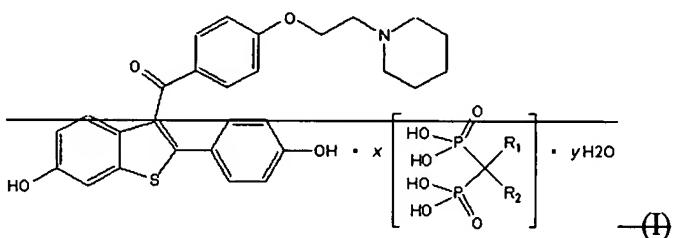
11. (currently amended): A pharmaceutical composition for preventing and treating osteoporosis comprising ~~the mutual salt of formula (I)the crystalline hydrate of raloxifene bisphosphonate of claim 4~~ as an active ingredient together with pharmaceutically acceptable carriers:

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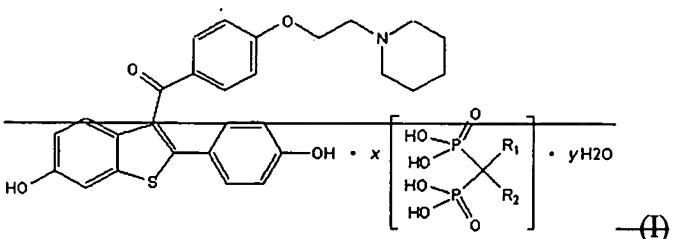
~~wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, x and y have the same meanings as defined in claim 1.~~

12. (currently amended): A pharmaceutical composition for preventing and treating hypercalcemia comprising the ~~mutual salt of formula (I)~~ crystalline hydrate of raloxifene bisphosphonate of claim 4 as an active ingredient together with pharmaceutically acceptable carriers:



~~wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, x and y have the same meanings as defined in claim 1.~~

13. (currently amended): A pharmaceutical composition for preventing and treating hyperlipidemia comprising the ~~mutual salt of formula (I)~~ crystalline hydrate of raloxifene bisphosphonate of claim 4 as an active ingredient together with pharmaceutically acceptable carriers:



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~~wherein R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, x and y have the same meanings as defined in claim 1.~~